DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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May 29, 2001

WARNING LETTER NO. 2001-NOL-25

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Fred J. Pollman III, President
Pollman's Bake Shops, Inc.
750 South Broad Street
Mobile, Alabama 36603

Dear Mr. Pollman:

We inspected your firm, located at 750 South Broad Street, Mobile, Alabama, on April 16 through 18, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21 *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at http://www.fda.gov.

The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for tuna salad sandwiches to control the food safety hazard of pathogen growth and toxin formation.

- You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for any of the following eight areas of sanitation:

  1. Safety of water;
  2. Condition and cleanliness of food contact surfaces;
  3. Prevention of cross-contamination;
  4. Maintenance of hand washing, hand sanitizing and toilet facilities;
  5. Protection of food, food packing material, and food contact surfaces from adulteration;
  6. Proper labeling, storage, and use of toxic compounds;
  7. Control of employees with adverse health conditions; and,
  8. Exclusion of pests.

In addition, the investigator documented numerous insanitary conditions that cause the non-seafood sandwich and bakery products you manufacture to be adulterated within the meaning of Section

402(a)(4) of the Act. They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth.

Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example:

1. They contacted insanitary equipment and then handled various products without washing or sanitizing their hands;
2. They routinely consumed food items in the processing area during operations; and,
3. They did not wear adequate hair restraints during operations.

Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated within the meaning of the Act. For example, the sandwich assembly table surface, which is pitted and nicked, is encrusted with a black foreign material and the meat-cutting machine is encrusted with material from previous operations.

These findings are further detailed in the enclosed Form FDA 483 that was discussed with you at the conclusion of the inspection.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your HACCP plan, sanitation monitoring records, and temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Carl E. Draper

Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483